ConMed Corporation
Orjada Dervishleri
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

July 3, 2019

Re: K191204
Trade/Device Name: Infinity™ Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 21, 2019
Received: June 21, 2019

Dear Orjada Dervishleri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Laurence Coyne, Ph.D.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191204

Device Name
Infinity™ Fixation System

Indications for Use *(Describe)*

The InfinityTM Fixation System is intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or reconstruction of a ligament using soft tissue grafts. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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CONMED CORPORATION

510(k) SUMMARY

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, CONMED Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number K191204.

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd
Largo, Florida 33773

Phone: 727-399-5491
Fax: 727-399-5264

Contact Person: Orjada Dervishleri
Date Prepared: May 3rd, 2019

II. DEVICE NAME

Device Name:	Infinity™ Fixation System
Classification Name:	Fastener, fixation, nondegradable, soft tissue
Regulatory Class:	Class II, per 21 CFR Part 888. 3040
Product Codes:	MBI

III. PREDICATE/ LEGALLY MARKET DEVICE

Device Name:	ConMed Linvatec XO Button
Company Name:	ConMed Linvatec
510(k) #:	K070780

IV. PREDICATE DEVICE

Device Name:	GraftMax™ Button, ALB (Adjustable Loop Button) and GraftMax™ Button, BTB (Bone-Tendon-Bone)
Company Name:	ConMed Corporation
510(k) #:	K151037

V. DEVICE DESCRIPTION

The CONMED Infinity™ Fixation System is a family of metal buttons and non-absorbable Hi-Fi suture for suspensory fixation of tendon to bone used in ligament reconstruction procedures. The Infinity™ Fixation System is provided individually packaged, single-use, sterile. The anchor, suture, and disposable driver are EO Sterilized.

VI. INTENDED USE/ INDICATIONS FOR USE

VII. The Infinity™ Fixation System is intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or reconstruction of a ligament using soft tissue grafts. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament.

VIII. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table represents a summary of the technological characteristics between the proposed and the predicate device.

	Infinity™ Fixation System Proposed Device	ConMed Linvatec XO Button Predicate Device	GraftMax Button, ALB with Cradle, GraftMax Button, BTB with Cradle Predicate Device
Device Description	The Infinity™ Fixation System is a family of metal buttons and non-absorbable Hi-Fi suture for suspensory fixation of soft tissue grafts to bone used in ligament reconstruction procedures.	Same	Same
Intended Use / Indication for Use	The Infinity™ Fixation System is intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or reconstruction of a ligament using soft tissue grafts. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament.	Same	The device may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.
Contraindications	1. Do not use the Infinity™ Fixation System for fixation of bone-patellar tendon-bone (BTB) grafts. 2. The Infinity™ Femoral Adjustable Loop Button is contraindicated for fixation of soft tissue in the tibial tunnel of ACL and PCL repairs. 3. Insufficient quantity or quality of cortical bone for fixation. 4. Blood supply limitations and/or previous infections, which may tend to retard healing. 5. Patients with active sepsis. 6. Conditions which tend to limit the patient's ability or willingness to follow directions during the healing period. 7. Foreign body sensitivity, known or suspected allergies to implant materials.	Same	1.Insufficient quantity or quality of cortical bone for fixation. 2.Blood supply limitations and/or previous infections, which may tend to retard healing. 3.Patients with active sepsis. 4.Conditions which tend to limit the patient's ability or willingness to follow directions during the healing period. 5.Foreign body sensitivity, known or suspected allergies to implant materials.

Components	Femoral button with pull tab Tibial buttons (2) Free loop Suture Cradle		Same
Technological Characteristics	Providing Suspension Fixation Pre-attached with sutures Lead strand suture to manipulate and position the button but not implanted Adjustable Loop technique Free Loop Adaptor for the button body	Providing Suspension Fixation Pre-attached with sutures Fixed Loop technique	Providing Suspension Fixation Pre-attached with sutures Adaptor for the button body

IX. PERFORMANCE DATA

Testing has been completed to demonstrate that the Infinity™ Fixation System performs as intended and is substantially equivalent to the predicate device. Bacterial endotoxin testing was conducted and met the endotoxin limits.

Completed testing includes the following:

Verification Testing

- Reliability
- Ultimate Fixation Strength
- Transportation
- Cyclic
- Pyrogen
- Biocompatibility
- Shelf-life

Validation Testing

- User Validation
- Packaging
- Labeling
- Sterilization

X. CONCLUSION

The Infinity™ Fixation System is either substantially equivalent or identical in design, materials, intended use, principles of operation, and technical characteristics to the predicate ConMed Linvatec XO Button. Based upon the findings of our performance testing, the differences present no new issues of safety and efficacy, and the Infinity™ Fixation System is substantially equivalent to the ConMed Linvatec XO Button (K070780).